Melissa E. Flax, Esq.
Michael Cross, Esq.
CARELLA BYRNE CECCHI OLSTEIN
BRODY & AGNELLO, PC
5 Becker Farm Road
Roseland, NJ 07068
(973) 994-1700
mflax@carellabyrne.com
mcross@carellabyrne.com

Attorneys for Defendant
Sagent Pharmaceuticals, Inc.

Stephen R. Auten, Esq.
Brian P. Murray, Esq.
TAFT STETTINIUS & HOLLISTER LLP
111 East Wacker Dr., Suite 2800
Chicago, IL 60601
312-527-4000
sauten@taftlaw.com
bmurray@taftlaw.com

Attorneys for Defendant
Sagent Pharmaceuticals, Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HELSINN HEALTHCARE S.A, Plaintiff, v. SAGENT PHARMACEUTICALS, INC., Defendant.	CA. No. 2-16-cv-00173 SRC-CLW **Filed Under Seal** **Oral Argument Requested**

BRIEF IN SUPPORT OF SAGENT'S MOTION TO
ENFORCE SETTLEMENT AGREEMENT

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I. INTRODUCTION

Pursuant to the Court's Order (D.I. 50)[1] Sagent Pharmaceuticals, Inc. ("Sagent") respectfully moves to:

> (i) enforce its Settlement and License Agreement ("Sagent Settlement") with Helsinn Healthcare S.A. ("Helsinn") [redacted]
>
> (ii) seek an order requiring Helsinn to produce its settlement agreements regarding generic ALOXI®, inclusive of amendments, with Dr. Reddy's Laboratories ("Dr. Reddy's"), and Sandoz, Inc. ("Sandoz").

This case, like the Dr. Reddy's and Sandoz case, concern generic versions of Helsinn's branded product ALOXI® injection, which has palonosetron hydrochloride as the active ingredient. Like Sagent, Dr. Reddy's and Sandoz both settled their respective patent infringement litigations with Helsinn. [redacted]

Sandoz and Dr. Reddy's, together with Teva Pharmaceuticals USA, Inc. ("Teva"), were the first ANDA sponsors to challenge at least one *Orange Book* patent listed for ALOXI®, and

[1] Helsinn also sued Sagent for infringement in Civ. A. No. 3-16-cv-00681 SRC-CLW. Although the Order (D.I. 50) is published in the present case, the relief requested herein by Sagent, for enforcement of its settlement agreement with Helsinn, is equally applicable to Civ. A. No. 3-16-cv-00681 SRC-CLW.

thus share the 180-day exclusivity. Teva was the first to trigger that exclusivity, launching its generic ALOXI® "at-risk" (*i.e.*, without a settlement agreement with Helsinn) on March 23, 2018. Dr. Reddy's launched on March 26th and Sandoz a few days later on April 2nd.

Helsinn has steadfastly tried to protect its market for ALOXI®, filing infringement actions against at least fifteen other ANDA sponsors in addition to Teva, Dr. Reddy's, Sandoz, and Sagent. Helsinn also tried to enjoin Teva's launch, but was denied. Surprisingly, Helsinn has not sought to remove Dr. Reddy's or Sandoz from the market, [redacted]

Importantly, Sagent Settlement [redacted]

Helsinn disagrees with Sagent's interpretation and [redacted] Moreover, the relief requested herein by Sagent will ensure compliance, [redacted]

Sagent filed a motion to reopen the case and for an order to show cause on May 11, 2018. (D.I. 46-47). The Court held a status hearing on May 15th, granting the motion to reopen the case, denying the motion for an order to show cause but inviting Sagent to file a motion to enforce the Sagent Settlement. (D.I. 50). We thus seek the Court's assistance in enforcing the Sagent Settlement.

II. STATEMENT OF FACTS

A. Helsinn Sues Sagent, Among Others, For Patent Infringement on ALOXI® (palonosetron HCl injection)

Helsinn owns New Drug Application ("NDA") No. 021372, which is directed to palonosetron hydrochloride injection and which Helsinn markets in the United States under the ALOXI® trade name. In connection with its NDA, Helsinn listed several patents with the U.S. Food & Drug Administration ("FDA") for publication in *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is commonly known as the "Orange Book." Such patents included those asserted in the instant cases, namely U.S. Patent Nos. 7,947,724; 7,947,725; 7,960,424; 8,598,219; and 8,729,094 (collectively, "the Asserted Patents").

On January 11, 2016, Helsinn filed the first action against Sagent (Civ. A. No. 16-173), after receiving notification that Sagent's Abbreviated New Drug Application ("ANDA") No. 205870, which referenced Helsinn's NDA, contained a so-called Paragraph IV Certification to each of the Asserted Patents. Helsinn filed a second complaint on February 8, 2016 (Civ. A. No. 16-681) (collectively, "the Litigations"), after receiving a similar notification as to Sagent's ANDA No. 204289. [redacted] Both ANDAs are directed to the dosage strength of Eq. 0.25 mg/base 5 mL (Eq. 0.05 mg base/mL).

Importantly, both ANDAs have received tentative approval from FDA, meaning that the drug products described in the applications are ready for final market approval but for a blocking exclusivity.[2] 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd); *see also* 21 C.F.R. 314.3(b). That exclusivity

[2] ANDA No. 204289 obtained tentative approval on August 7, 2017, and ANDA No. 205870 obtained tentative approval on April 20, 2018. *See* Exs. 1 and 2. (The Exhibit Nos. correspond to the exhibits listed in the Declaration of Roshan P. Shrestha, Ph.D. ("Shrestha Decl.") submitted herewith.

is the 180-day market exclusivity, which is granted to the first ANDA sponsors to file an application with a Paragraph IV Certification to a patent listed in the Orange Book for the reference listed drug. 21 U.S.C. § 355(j)(5)(B)(iv); *see also* 21 C.F.R. 314.3(b).

Here, that exclusivity is shared by Teva, Dr. Reddy's, and Sandoz, all of which have launched their respective generic ALOXI® products in the same dosage strength as Sagent's ANDAs, thus triggering the 180-day exclusivity. No other ANDA sponsor, including Sagent, will be granted final FDA approval until that exclusivity is exhausted. That exclusivity expires on September 19, 2018, [redacted]

B. Sagent and Helsinn Settled the Litigations

On [redacted] Helsinn and Sagent signed the Sagent Settlement, resolving the Litigations between them. [redacted] Accordingly, both actions were dismissed on August 2, 2016 (Ex. 4, D.I. 39 for Civ. A. No. 16-173, and Ex. 5, D.I. 27 for Civ. A. No. 16-681) pursuant to a Consent Judgment and Dismissal that was substantially the same in both Litigations, referencing the Sagent Settlement and noting that the "court retains jurisdiction over Helsinn and Sagent for purposes of enforcing this Consent Judgment and Dismissal Order." ("Sagent Dismissal Orders"); [redacted] specifying the terms of the consent judgment and dismissal order.

Under the terms of the Sagent Settlement, [redacted]

[redacted]

[3] Another such circumstance is where [redacted]

[redacted]

C. Teva Launches the First Generic ALOXI® At-Risk

Before Sagent, Teva also had filed an ANDA referencing Helsinn's NDA for ALOXI® and, over time, with a Paragraph IV Certification to each of the Asserted Patents.[4,5] As noted

[4] Teva's ANDA (like Sandoz's and Dr. Reddy's) was filed on May 27, 2011. *See* Ex. 8 (FDA's list of first applicants, noting the filing date relevant to ALOXI®). As Teva, Dr. Reddy's, and Sandoz share the 180-day exclusivity, it necessarily follows that all three filed on this date. 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb). Accordingly, Helsinn's first lawsuit against generic ALOXI® sponsors was against Teva, Dr. Reddy's, and Sandoz. *See Helsinn Healthcare S.A. v. Dr. Reddy's Laboratories, Ltd.*, Civ. A. No. 3:11-cv-03962 (D. N.J. filed July 8, 2011) (asserting the '724 and '725 patents).

[5] When Teva's, Dr. Reddy's, and Sandoz's ANDAs were filed, the *Orange Book* listed only the '724 and '725 patents. The remaining Asserted Patents were listed later, requiring the ANDA sponsors to file Paragraph IV Certification to each of those patents to secure final FDA approval before patent expiration. When Helsinn was notified of those certifications, it filed suit accordingly. These details are not needed for the instant motion but are provided to ensure an accurate recitation of facts. *See, e.g., Helsinn Healthcare S.A. v. Dr. Reddy's Laboratories, Ltd.*, Civ. A. No. 3:11-cv-05579 (D. N.J. filed Sep. 23, 2011) (asserting the '424 patent against all three first applicants); *Helsinn et al. v. Dr. Reddy's et al.*, Civ. A. No. 3:13-cv- 05815, D.I. 27 (D. N.J. filed Sep. 30, 2013) (asserting the '219 patent against all three first applicants); *Helsinn et al. v.*

above, Teva along with Dr. Reddy's and Sandoz were the first ANDA sponsors for generic ALOXI®, entitling them to share the 180-day exclusivity. Teva's ANDA No. 090713 received final FDA approval on March 23, 2018, and Teva launched the same day. *See* Ex. 9, Teva's Press Release dated March 23, 2018 at p. 4 (noting the shared exclusivity). Helsinn was denied an injunction to stop Teva's launch. Ex. 10, Civ. A. No. 14-4274, D.I. 89 (D. N.J. Jan. 30, 2018). To date, Sagent is not aware of any settlement agreement between Helsinn and Teva, thus making Teva's launch "at-risk" for patent damages.[6]

D. Dr. Reddy's and Sandoz Both Launch Generic ALOXI® [redacted]

Helsinn sued Dr. Reddy's and Sandoz along with Teva in the same complaint in its initial action against the first sponsors of generic ALOXI® followed by later-filed cases against the same three sponsors after receiving notice of Paragraph IV Certifications to the patents subsequently listed in the *Orange Book*. In late 2014, Helsinn and Sandoz resolved their dispute, executing a settlement agreement and resulting in Consent Judgment and Dismissal Order, which expressly enjoined Sandoz:

> from manufacturing, using, offering to sell or selling within the United States, or importing into the United States, any generic palonosetron hydrochloride injections (Eq. 0.075 mg base/1.5 mL (Eq. 0.05 mg base/mL) and/or Eq. 0.25 mg base/5 mL (Eq. 0.05 mg base/mL)) that are the subject of ANDA No. 202521 ***except as permitted*** by the Settlement and License Agreement that the Parties have entered into.

Dr. Reddy's et al., Civ. A. No. 2:14-cv-04274, D.I. 1 (D. N.J. filed Jul. 7, 2014) (asserting the '094 patent against Teva and Dr. Reddy's but not Sandoz).

[6] The Court of Appeals for the Federal Circuit has held invalid the asserted claims of four of the Asserted Patents, on which Helsinn has filed a petition for a writ of certiorari. *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 355 F.3d 1356 (Fed. Cir. 2017). Helsinn continues to assert the remaining Asserted Patent, the '094 patent, against Teva. *See* Civ. A. No. 3:14-cv-06341 (D. N.J. filed Oct. 13, 2014) now consolidated with 2:14-cv-04274.

Order dated Dec. 30, 2014 at pp. 3-4 in Civil Action No. 2-11-cv-03962 (D.I. 247) (Ex. 11, the "Sandoz Order") (emphasis added). Sandoz's settlement allowed it to launch on September 30, 2018, or earlier under certain circumstances. Ex. 12, Helsinn Press Release dated January 12, 2015, at p.1. Such circumstance arose, as Sandoz launched on April 2, 2018 (Ex. 13, Salazar, D., "Sandoz Launches Its Aloxi Generic," Drug Store News, Apr. 2, 2018 at p. 2) its product having the same dosage strength as Sagent's ANDA [redacted] Although Sandoz's FDA approval letter did not confirm the 180-day exclusivity at that time, there also was no confirmation of forfeiture either. Ex. 14 (Sandoz's final FDA approval letter).

Dr. Reddy's facts are similar. On October 6, 2015, Helsinn likewise signed a settlement agreement with Dr. Reddy's, later dismissing their case with Dr. Reddy's enjoined:

> from manufacturing, using, offering to sell or selling within the United States, or importing into the United States, any generic palonosetron hydrochloride injections (Eq. 0.075 mg base/1.5 mL (Eq. 0.05 mg base/mL) and/or Eq. 0.25 mg base/5 mL (Eq. 0.05 mg base/mL)) that are the subject of ANDA No. 201533 ***except as permitted*** by the Settlement and License Agreement that the Parties have entered into.

Ex. 15 at p. 2 (Stipulation of Dismissal entered Oct. 16, 2015 in Civ. A. No. 2-11-cv-03962, D.I. 355) (the "Dr. Reddy's Order") (emphasis added). Like Sandoz, Dr. Reddy's settlement allowed it to launch "on September 30, 2018 or earlier under certain circumstances." Ex. 16 at p. 1, Helsinn's Press Release dated Oct. 13, 2015. Such circumstance indeed arose, as Dr. Reddy's launched its generic ALOXI®, in the same dosage strength as Sagent's ANDAs, on or prior to March 26, 2018 (Ex. 7), [redacted] Finally, Dr. Reddy's approval letter confirmed the 180-day exclusivity. Ex. 17 at p. 2 (stating that "Dr. Reddy's is eligible for 180 days of shared generic drug exclusivity for Palonosetron Hydrochloride Injection … 0.25 mg (base)/5 mL").

E. Sagent Requested Helsinn to Confirm

On April 4, 2018, Helsinn responded

After several rounds or discussion, on April 27th, Helsinn's counsel advised that

[7] By contacting Helsinn Sagent acted without delay. The same is true as to filing the motion

[8] Ex. 21.

[redacted] Ex. 22, Email from E. Dittmann to S. Auten dated Apr. 27, 2018. On May 3rd Sagent requested Helsinn's [redacted]. Ex. 20, Email thread between S. Auten and E. Dittmann (Helsinn) dated May 8, 2018.

F. Dr. Reddy's [redacted] and Sandoz [redacted]

Separately, Sagent also wrote to outside counsel of record and/or in-house counsel for Dr. Reddy's and Sandoz, [redacted]. Ex. 23, Ltr. from S. Auten to A. Miller dated Apr. 4, 2018 (Dr. Reddy's); and Ex. 24, Ltr. from S. Auten to E. Abraham dated Apr. 5, 2018 (Sandoz). Counsel for Dr. Reddy's [redacted] Ex. 25, Email from F. Rodriguez to S. Auten dated Apr. 25, 2018. Sandoz's outside counsel responded [redacted] (Ex. 26, Email from E. Abraham to S. Auten dated Apr. 19, 2018), and two additional queries to Sandoz's corporate officers [redacted]. Ex. 27, Ltr. from S. Auten to M. Quinn *et al*. dated Apr. 19, 2018; and Ex. 28, Email from S. Auten to M. Quinn *et al.* dated Apr. 25, 2018.

G. Sagent Faces Irreparable Harm of [redacted]

[redacted] Declaration of Donald R. Bullock at ¶ 23 ("Bullock Decl.").

[redacted] *Id*. at ¶ 22.

Id. at ¶ 24.

[redacted].

Further, only the following five other ANDA sponsors have tentative approval at present and have settled their cases with Helsinn: Aurobindo Pharma Ltd.; Akorn, Inc.; Qilu

Pharmaceutical Co., Somerset Therapeutics, LLC, and Fresenius Kabi USA, LLC. As of today, they are the only other ANDA sponsors able to receive final FDA approval at the same time as Sagent, once the 180-day exclusivity expires. *Id.* at ¶ 31. But additional competition is expected in the future, as Helsinn is known to have sued at least fifteen other ANDA sponsors.[9] That means an additional ten other ANDAs (or more) could also receive final approval in the future, assuming their applications meet FDA requirements. *Id.* [redacted] *Id.* at ¶ 32. [redacted]

III. LEGAL STANDARD

A. This Court Has Authority to Enforce Settlement Agreement

This court has the inherent power to enforce settlement agreements. *See Kelly v. Greer*, 365 F.2d 669, 671 (3d Cir. 1966) (collecting cases). Indeed, there is a strong public policy favoring settlement, and requiring parties to honor settlement agreements. *See Honeywell v. Bubb*, 130 N.J. Super. 130, 135-36 (App. Div. 1974) ("Embedded in our jurisprudence is the principle that the

[9] Other ANDA defendants sued by Helsinn in this District or Delaware include: Aurobindo Pharma Ltd. (D. Del. 13-688); Ben Venue/Eurohealth (D. Del. 13-1612); Accord Healthcare, Inc. (D. Del. 13-2101); Cipla, Ltd. (D. Del. 14-427); Hospira, Inc. (D. Del. 15-264); Gavis Pharma, LLC (D. N.J. 15-1228); Mylan Inc. (D. Del. 14-709); Par Pharmaceutical Cos. (D. N.J. 15-2078); Qilu Pharma. Co., Ltd. (D. N.J. 15-8132); Emcure Pharma., Inc./Heritage Pharma Labs, Inc. (D. N.J. 15-7015); Akorn, Inc. (D. N.J. 16-173); Ingenus Pharma., LLC (D. N.J. 16-173); Virtus Pharma., LLC (D. N.J. 17-3216), Zydus Pharma. USA, Inc. (D. N.J. 16-4239); Fresenius Kabi. (D. N.J. 15-2077, 15-7015; 15-7378).

settlement of litigation ranks high in our public policy …. Thus, barring fraud or other compelling circumstances, our courts strongly favor the policy that the settlement of litigation be attained and agreements thereby reached, be honored."); *Nolan v. Lee Ho*, 120 N.J. 465, 472 (1990). Here, the Sagent Dismissal Order specifically provides that this Court retain jurisdiction over the parties for the purposes of enforcing the consent judgment and dismissal order, [redacted] *See e.g.*, Ex. 4, Civ. A. No. 16-173, D.I. 39 at p. 3; *Halderman v. Pennhurst State School & Hosp.*, 901 F.2d 311, 317 (3d Cir. 1990).

B. State Contract Law Governs the Interpretation of the Settlement Agreement

Settlement agreements are interpreted as binding contracts. *In re Columbia Gas Sys. Inc.*, 50 F.3d 233, 238 (3d Cir. 1995). The principles of contract law govern the enforceability and construction of these agreements, in which the primary object is to give effect to the intention of the parties. *Id.* at 241 (internal citations omitted); *Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, Civ. A. No. 07-2762, 2009 WL 3230867, at *2 (D. N.J. Oct. 2, 2009); *Coltec Industries v. Hobgood*, 280 F.3d 262, 269 (3d Cir. 2002) ("[B]asic contract principles . . . apply to settlement agreements"). Absent clear language in the settlement agreement to resolve a dispute over the proper construction of a contract, a court may go outside the four corners of the contract and consider extrinsic and parol evidence presented by the parties. *In re Columbia*, 50 F.3d 233, 241. [redacted]

C. Requirements for Finding an Enforceable Agreement

The party moving for enforcement of a settlement agreement bears the burden of showing the existence of the agreement by a preponderance of the evidence. *Fazio v. Temp. Excellence, Inc.*, Civ. A. No. A-5441-08T3, 2012 WL 300634, at *5 (N.J. Super. Ct. App. Div. Feb. 2, 2012) *citing Amatuzzo v. Kozmiuk, 305 N.J.Super*. 469, 475, 703 A.2d 9 (App.Div.1997). Whether an

enforceable settlement exists requires analyzing first, whether the requisite offer, acceptance, and consideration were present; and second, whether an objective reasonable negotiator, in light of all the circumstances, would conclude that the parties intended to be bound by their agreement on the essential terms. *See e.g.*, *Thorner v. Sony Computer Entm't Am. LLC*, Civ. A. No. 09-1894 MLC, 2013 WL 1145200, at *5 (D. N.J. Mar. 18, 2013) (internal citations omitted); *Sanofi*, 2009 WL 3230867, at *2. "[J]udicial admissions are good evidence that an agreement ha[s] been made." *Philadelphia Reinsurance Corp. v. Employers Ins. of Wausau*, 61 Fed. Appx. 816, 819 (3d Cir. 2003) quoting *ALA, Inc. v. CCAIR, Inc.*, 29 F.3d 855, 862 (3d Cir.1994).

"Ratification is the affirmance by a person of a prior act which did not bind him but which was done…, whereby the act… is given effect as if originally authorized by him." *Friedman v. Bank of Am., N.A.*, Civ. A. No. 09-2214 JBS, 2012 WL 1019220, at *6 (D. N.J. Mar. 26, 2012) (citations omitted). To establish ratification, the person must be shown to have (1) an intent to ratify, and (2) full knowledge of all material facts. *In re Dwek*, Civ. A. No. ADV 07-1616 KCF, 2011 WL 843635, at *7 (D. N.J. Mar. 8, 2011). Ratification of an agreement "may be express or implied, and intent may be inferred from the failure to repudiate an unauthorized act, from inaction, or from conduct on the part of the principal which is inconsistent with any other position than intent to adopt the act." *Friedman*, 2012 WL 1019220, at *6; *Valmed Mgmt. Corp. v. Jess Med. Sys.*, Civ. A. No. A-2947-05T1, 2007 WL 148752, at *6 (N.J. Super. Ct. App. Div. Jan. 23, 2007). Importantly, "a ratification, once effected, cannot later be revoked." *Friedman*, 2012 WL 1019220, at *6.

IV. ARGUMENTS

A. [redacted]Dr. Reddy's and Sandoz's Launches of Generic ALOXI®

Helsinn contends [redacted] Ex. 19. But that conclusion is belied by the following facts.

First, t[redacted]. Exs. 15 at p. 2 and 11 at p. 2. [redacted]

Second, [redacted]

Third, [redacted] *See, e.g., Valmed*, 2007 WL 148752, at *6[redacted]; *Friedman*, 2012 WL 1019220, at *6; *see also* [redacted]

For comparison, shortly before Teva launched its product at-risk, [redacted] Ex. 10, Civ. A. No. 14-4274, D.I. 89 (D. N.J. Jan. 30, 2018). [redacted] Bullock Decl. at ¶ 9-10. [redacted]

This is almost assured because [redacted]

B. Dr. Reddy's and Sandoz's Launches Trigger Acceleration of Sagent's Entry Date

Sagent's "License Effective Date" or its entry date [redacted] Ex. 17 at p. 2; Ex. 14 at p. 2. [redacted]

[redacted] *Valmed*, 2007 WL 148752, at *6. Therefore, [redacted]

C. Helsinn's Settlement Agreements with Dr. Reddy's and Sandoz are Relevant and Therefore, Must be Produced

The Sagent Settlement [redacted] It is undisputed that Helsinn has entered into a settlement agreement with both Dr. Reddy's and Sandoz and as explicitly stated in their respective dismissal orders. *See* Ex. 15 at p. 2 and Ex. 11 at p. 4, respectively. *Philadelphia Reinsurance*, 61 Fed. Appx. At 819. Further, it is established that [redacted]

Helsinn's agreements with Dr. Reddy's and Sandoz thus become relevant to assist the court and the parties to articulate Sagent's entry date. *In re Columbia*, 50 F.3d at 241 (holding that the Court may go outside the four corners of the contract and consider other evidence). This court has compelled production of confidential settlement agreements in Hatch Waxman cases. *Pfizer et al. v. Mylan et al.*, Civ. A No. 10-CV-03246, 2012 WL 13034382 (D. N.J. Jan. 4, 2012); *Wyeth v. Orgenus Pharma Inc.*, Civ. A. No. 09-3235 (FLW), 2010 WL 4117157, at *4 (D. N.J. Oct. 19, 2010). Therefore, the Court should compel the production of Helsinn's settlement agreements with Dr. Reddy's and Sandoz.

D. The Agreements Could Be Produced to Outside Counsel Only, [redacted]

As Helsinn's counsel stated [redacted] *See also*, Ex. 22, Email from E. Dittmann dated April 27, 2018. However, confidentiality obligations between private parties cannot affect the discoverability of such agreements in a subsequent litigation. *Pfizer*, 2012 WL 13034382 at *2; *see also Thomas & Marker Constr. Co. v. Wal-Mart Stores, Inc.*, Civ. A. No. 06-406, 2008 WL 3200642, at *3 (S.D. Ohio Aug. 6, 2008) (compelling production of confidential settlement agreement over, among others, the confidentiality objection of the plaintiff); *Sonnino v. Univ. of Kan. Hosp. Auth.*, Civ. A. No. 02-2576, 2004 WL 769325, at *3 (D. Kan. April 8, 2004) ("litigants cannot shield otherwise discoverable information from disclosure to others by agreeing to maintain its confidentiality, and cannot modify the Federal Rules of Civil Procedure by agreement."). As noted by Magistrate Judge Arpert, "other courts have routinely recognized that license agreements relating to patents-in-suit, and entered into in connection with settlement, are discoverable" because "third party confidentiality concerns do not outweigh legitimate grounds to compel production." *Wyeth*, 2010 WL 4117157, at *4 (citations omitted).

[redacted] By agreeing to receive the agreements on an outside-attorneys'-eyes-

only basis, Sagent has agreed to maintain the information in accordance with the highest tier of standard protective orders.

E. Sagent will Suffer Irreparable Harm

1.

A manufacturer that is prevented from entering the market at the earliest possible date, because a competitor is permitted to capture an early market entry, is at a distinct disadvantage. *See*, *Mova Pharm. Corp. v. Shalala*, 955 F. Supp. 128, 131(D. D.C. 1997), *aff'd*, 140 F.3d 1060 (D.C. Cir. 1998). Both of Sagent's ANDAs have tentative approval, Exs. 1, 2, and 21. *Id.* at ¶ 24.

[redacted] *Id*.

[redacted] *Id*. at ¶¶ 25, 27-30.

[redacted] *Id*. at ¶ 31. At present, only five other ANDA sponsors have tentative approval and have settled their cases with Helsinn, [redacted] But because Helsinn has sued at least fifteen other ANDA sponsors, then as many as eleven other ANDAs (or more) could also receive final approval in the future. [redacted].

2. The Sagent Settlement Includes [redacted]

V. CONCLUSION

For the reasons detailed above, Sagent respectfully moves this court to enforce its settlement agreement with Helsinn by declaring that its market entry date has been accelerated to [redacted] and order Helsinn to produce its settlement agreements, inclusive of amendments, with Dr. Reddy's and Sandoz.

Dated: May 23, 2018

\s\ Melissa E. Flax__
Melissa E. Flax, Esq.
Michael Cross, Esq.
CARELLA BYRNE CECCHI OLSTEIN BRODY & AGNELLO, PC
5 Becker Farm Road
Roseland, NJ 07068
(973) 994-1700
mflax@carellabyrne.com
mcross@carellabyrne.com

Of Counsel
Stephen R. Auten, Esq.
Brian P. Murray, Esq.
TAFT STETTINIUS & HOLLISTER LLP
111 East Wacker Dr., Suite 2800
Chicago, IL 60601
312-527-4000
sauten@taftlaw.com
bmuarry@taftlaw.com

Attorneys for Defendant
Sagent Pharmaceuticals, Inc.